PRESENTATION FROM MICHIGAN DEER AND ELK FARMERS ASSOCIATION

SUBMITTED BY DANIEL P. MARSH, EXECUTIVE DIRECTOR
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Thank you for allowing the opportunity for input to assist this task force in making fully informed recommendations to Governor Granholm concerning CWD. Recommendations for action concerning CWD may pose significant challenges for the relevant agencies, industry, and the people of Michigan.

If you agree animal health is typically regarded as a scientific pursuit, then you would agree our understanding of the etiology and response to disease is heavily influenced by scientific inquiry.

To date, science has provided more questions than answers concerning CWD, and has failed to provide appropriate support to state agencies for disease control and causation determination. To date, there has not been a comprehensive formal risk assessment using the scientific method concerning CWD. A review of current literature on the issue provides an indication of what is known so far about transmission of CWD. By way of summary, it appears CWD occurs in the following species via a natural route, i.e., oral feeding;

Cervids

Ferrets

Transmission of CWD by injecting the animals directly into the brain (a very efficient route, but definitely not a natural route)

Cattle (1/4 get infected with a TSE disease)

Cervids

Sheep

Ferrets

Mice (very inefficient even in mice in which the mouse prion gene is replaced by a cervid prion gene

CWD appears to be a very difficult transmissible spongiform encephalopathy to transmit to another species. There is a strong caveat here though. It may infect the "new" species but at a subclinical level in which a subsequent passage to another animal of the same species may cause disease to develop.

In vitro work done by Byron Caughey's laboratory on transmission of CWD from cervids are very inefficient in converting human, bovine and sheep normal prion protein to the abnormal form in a test tube. This indicates that at a molecular level, it is a very unfavorable reaction which means that cross species transmission is unlikely.

The situation with BSE is different. In mice that have had their prion gene changed for that of a cow, sheep or human, it is possible as described by Dr. Bosque to readily convert the bovine prion by variant CJD and vice versa - to convert the human gene by BSE. This demonstrates that BSE can convert the human prion protein to the abnormal form and can transmit. BSE is a bit different than most TSEs in that it crosses some species quite readily. This is rather unusual in this field.

Some of the governmental recommendations already are common sense - don't consume infected animals, destroy the contaminated animals, etc., test animals that die or are slaughtered, etc. Until there is a good pre-clinical test, this seems all that can be done.

Unfortunately, we must rely upon that science to guide agency action, regulation, and policies in areas of animal health. Realistic recommendation from this task force to Governor Granholm should include a formal risk assessment be conducted and completed before any recommendations made in regards to agency action, regulation, and policies are acted upon by government officials.

The challenge is not whether the recommendations are valid, but whether any governmental action in response to those recommendations regarding risk assessment, interpretive judgments, or scientific paradigms are defensible, appropriate, and scientifically valid.

We understand that the regulatory agencies involved concerning CWD are making risk assessments based on scientific paradigms that are incomplete at best and questionable at worst. In the event an agency is challenged to defend whether their decision is based on valid and legitimate scientific evidence, a proper foundation for the agency decisions that are reached should be documented. It is not enough that the agency makes an educated prediction based on the best available scientific evidence and resources and issues regulations based upon them. Eventhough these predictions are naturally going to be incomplete, they may still be called upon to withstand judicial scrutiny.

Animal health policies and regulations recommended that burden individual rights may implicate the Due Process Clause of the State Constitution. Animal health statutes provide for fair procedures in the exercise of coercive health powers, including written notice of the conditions said to pose a risk, assistance of counsel, a full and impartial hearing, and an appeal. The agency involved should be required to prove the existence of a health threat by clear and convincing evidence. These rigorous procedures are justified by the potential restriction on an individual's protected right to use and enjoy their private property for an extended period of time and the potential for erroneous fact-finding by the agency. Task Force recommendations may include updating necessary statutes to provide for these procedures that will eliminate the expense and confusion that arises when a court must assess the validity of a measure that is clearly necessary to control a significant animal health risk but was carried out under faulty statutory procedures.

We have heard it said by a conservation/environmental organization that it is far better to preempt any harms than under regulation would present and err on the side of over regulation. Policies that encourage an agency to over regulate may have as a consequence the agency merely addressing a threat in a manner where benefits are so marginal that the spending no longer justifies the cost of the additional regulation. We must prevent that type of agency decision-making in Michigan. But, by the same token if an agency under regulates, the harm complained of may have been avoided by more

regulation. The only way for agency action to reconcile this dilemma is to base such agency action on scientific principals and procedures.

Unless it is recognized that inconsistencies may occur if regulation concerning CWD are not examined in a broader context, an agencies regulation of one environmental risk may increase the danger posed by a collateral risk. For example, the U.S. import ban put in place in response to BSE, or "Mad Cow", in Canada has caused severe economic damage to the cattle industry and related industries supporting that industry (corn, hay, transportation, etc...) in that country. Officials are seeking policies and regulations that allow Canadian beef to cross the border. One of the measures proposed is "testing out" for BSE. Opponents to the proposal respond that government policies should remain consistent and do what the government did with discovery of CWD in privately owned cervidae in Canada---stop all movement and sales of animals and their commodities and to do otherwise is strictly a decision based on economics and not wild herd or human health concerns. Since BSE has been determined to hurt people and CWD has not, how can the government justify treating the more harmful in a less restrictive manner than the least harmful?

We must be mindful that different agencies do not asses the same risks differently. When these identical risks are valued differently, the possibility of agency economic miss-allocation increases. For example, when risks are regulated differently from two different agencies, there is a possibility that either one agency is over or under regulating. To reduce the likelihood of this situation, an inter-agency supported, scientifically based risk assessment is appropriate.

When an agency appears to react to disease issues and fail to provide a scientifically defensible foundation for action, confusion in the public results and credibility of the agency is in question. On Nov 12 a Food and Drug Administration (FDA) announcement was issued that no CWD positive carcasses should be used in any animal feed. An amendment clarifying the announcement was made on Nov 21. The stated policy is that no CWD positive animals can be used in any animal feed. The later amendment included

animals from an endemic area or eradication areas (tested or not). The message to the public is venison is not fit for pet food nor is safe for humans. This policy is not supported in other government polices nor science, and appears to be a reaction to media generated hysteria (a non-scientific source of information).

Overall, FDA is recommending that any material from deer and elk considered to be at high risk for CWD not be used in any animal feed or feed ingredients. High risk deer and elk are those from 1) areas declared by state officials to be endemic for CWD and/or to be CWD eradication zones and 2) those that at some time during the 60-month period before the time of slaughter were part of a captive herd with a CWD-positive animal.

The announcement was made at the request of the rendering industry. The rendering industry is apparently very concerned about future recalls surrounding venison and probably will exclude deer/elk offal or carcass material from rendering to avoid possible future recall action. Without rendering, the disposal of deer/elk offal is limited. The timing of the announcement was considered poor as deer and elk hunting season was already underway in many states.

Concerns about the inconsistency and misguided announcement is illustrated by the following;

* the same decision will not be applied to sheep and scrapie. The stated reason is there is more history with scrapie than CWD eventhough scrapie is theorized by some to be the cause of BSE and CWD (is it wise to dismiss scrapie as a problem?)

* Why are test negative animals from endemic areas being excluded from rendering when test negative animals in Europe are allowed to enter the food chain? (if the test has been completed before the carcass is presented, why exclude animals from endemic areas?)

*Agencies conducting surveillance and monitoring by collecting heads at processing plants for testing are encountering processors that are reluctant to participate. This announcement has impeded government ability to conduct surveillance for CWD.

*This announcement disfavors surveillance in states that are not endemic, no testing favors rendering (less chance of a recall).

*The FDA does not have mandatory authority over recalls. Alliances with state agencies are necessary for that authority.

*Since the FDA does not have authority over negative animals, the wording is "strongly advised" instead of a mandatory prohibition for venison being used in feed.

*The FDA does not regulate animals that are hunter-killed and self-processed.

*We do not if the ban applies to all cervid species (i.e. red deer, sika, reindeer), or to farmed deer within an endemic area,

*This announcement was issued without an environmental risk assessment. The FDA is proposing to contract a similar risk analysis as the Harvard BSE study

*The announcement was made against current scientific knowledge. With 50 years of experience in areas with higher prevalence, the decision to exclude deer/elk from rendering for poultry or swine feeds fails to consider the species barrier and facts from experience (no livestock infected).

State veterinarians throughout the country have been meeting to discuss the inconsistencies and appropriateness of this announcement. Further, The FDA has issued a draft guidance that will be the basis for FDA recommendations regarding the use of deer and elk ruminants in animal feed to help control the spread of CWD. The draft, titled "Use of Material from Deer and Elk in Animal Feed," is posted at:

http://www.fda.gov/cvm/guidance/dguide158.pdf.

FDA's guidance documents are not regulations, but rather voluntary recommendations. This draft guidance is being distributed for comment only. Written comments on the draft guidance were to be submitted by June 16, 2003 to ensure their adequate consideration in preparation of the final document.

The United States Department of Agriculture (USDA) Marketing and Regulatory Programs, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Center for Import and Export USDA's has banned the movement of "trophies" from Canada supposedly in response to the confirmed case of bovine spongiform encephalopathy (BSE). This will hurt hunting in Canada since many hunters cannot bring back the meat. Meat hunting is socially acceptable, while trophy hunting lacks support of the non-hunting populace. Now, the only reason to go hunting in Canada is for the "socially un-acceptable" hunting for antlers.

Some other state agencies are now stating they have conducted their own risk assessment concerning CWD. However, an agency lead risk assessment may not withstand substantive review by a court. Agencies have proven to be more susceptible to political influences than the judiciary. Furthermore, some members of regulatory agencies are appointed for limited terms and serve at the pleasure of the Governor of the State or the continuation of their position is influenced by the Governor. Often based on methods of data collection which are untried or novel, and often based on crossed disciplinary interpretive judgments, agency risk assessments generally lack the institutional credibility of normal science.

Since the cervidae production industry is the subject of concern by various administrative agencies, interpretations of scientific evidence have an enormous impact on the privately owned cervid production industry, since agency determinations of risk usually entail costly restructuring of industry standards in order to comply with any new regulations

that are based on the agencies interpretations of risk. Without fear of having to justify its sources of scientific evidence, an agency has virtual free rein unchecked powers with respect to determinations of risk. Without any substantive criteria for assessing the validity of the scientific sources used by agencies, agencies may naturally succumb to pressures that they err on the side of overprotection and moreover, especially at the margin, where costs sky rocket in relation to benefits, we have to make sure we don't misdirect or inefficiently expend hundreds of thousands (millions?) of dollars in pursuit of environmental, health and safety protection. Tunnel vision, a classic administrative disease arises when an agency effectively carries single-minded pursuit of a single goal too far, to the point where it brings about more harm then good. We must beware of recommending standards so stringent that the regulatory action ultimately imposes high costs without achieving significant additional safety benefits.

When an agency is justifying its determination for the level of risk, they must offer evidence that can allow an examination for the nexus between the evidence that is relied upon and the ultimate decision reached by the agency. We ask that you recommend that agencies provide explicit explanation for the basis of the agencies decision. This recommendation, if followed, will facilitate proper judicial review but also provide the opportunity for effective peer review, legislative oversight, and public education. This recommendation is in the best interest of everyone, including the decision makers themselves. If the decision making process is open and candid, it will inspire more confidence in those who are effected. Further, by opening the process to public scrutiny, we reduce the risk that importation information will be overlooked or ignored.

To rely upon evidence other than science can erode government credibility once the information subsequently becomes clarified. We are seeing examples of misinformation in the press regarding research concerning TSEs. An article in the New York Times (June 10, 2003 by Sandee Blakeslee) misquoted a TSE researcher that has led to other media publications quoting that article seeking to explain a connection between CWD and humans. One of the most inflammatory statements printed in the article stated "The results are often confusing, Dr. Bosque said. Mice with human prion genes get chronic

wasting disease but not mad cow disease, while humans get mad cow disease but not chronic wasting disease, so far"

Dr. Bosque, the person quoted, has since disclaimed that quote. The clarification on that statement is that mice with human genes are not particularly susceptible to vCJD (they get it, but transmission is not as efficient as is sporadic CJD, which is so rare it is not considered a significant risk of harm to the public). Mice (humanized transgenic, bovinized transgenics and non-transgenics) do not seem to get CWD. Dr Bosque inoculated many mice intracerebrally, (over a hundred, he believes), with homogenates of deer and elk with CWD and none developed signs of prion disease. What Dr. Bosque was talking about was what happens when he inoculated vCJD into humanized mice versus what happens when he inoculated vCJD into bovinized mice- the bovinized mice are much more susceptible to vCJD than are the humanized mice. This is considered odd, since the PrP amino-acid sequence of the inoculum is human (since the inoculum is prepared from the brains of human victims of vCJD). This misquote has caused a "stir" in the media and we are now seeing other reporters using the article to support assertions that evidence exist that CWD can infect humans. (contact information; Patrick Bosque, MD, Division of Neurology, Denver Health, M/C 4000, Denver CO 80204-0457, tel. 303-436-6899, fax. 303-436-7249, e-mail: patrick.bosque@dhha.org).

The are other media reports seeking to connect Transmissible Spongiform Encephalopathy to many ruminants beyond cattle (BSE) and sheep (scrapie); for example, eland, the Arabian oryx, the greater kudu, the gemsbok, the nyala, the scimitar-horned oryx, the ankole, bison, mink, and ostriches. One published article by the Canadian Hemophilia Society states these animals were infected in the same way as British cattle - through eating BSE-infected feed. The attempt to make such connections does stop with captive wild ruminants, it also includes pets; feline spongiform encephalopathy (FSE) in a Siamese cat and a large number of other cats are claimed to have been affected to include; puma, cheetah, ocelot and tiger. One case was cited from Italy about a domestic cat and his human master both coming down with CJD at the same time.

We have seen media reports attempting to link CWD cases in captive and free-ranging cervids in Wisconsin. We do have scientific research that positive captive deer in Wisconsin are likely not the source of CWD in the free-ranging White-tailed Deer outbreak because of the captive deer's distance from the area where the CWD-positive free-ranging deer are (approximately 130 km) and the fact that no direct evidence exists that CWD came to Wisconsin by the captive cervid industry. (See Chronic Wasting Disease in Free-Ranging Wisconsin White-Tailed Deer, United States Geological Survey-Wisconsin Cooperative Wildlife Research Unit)

We know that CWD does not harm humans, does not effect other livestock, and is not diminishing wildlife populations (in fact they are growing even in the Colorado endemic area). Also, there is no doubt this disease is being brought over the boarders from out-of-state hunters. In mid-October, 2002, an estimated 1700 hunter-submitted deer and elk heads were tested in Colorado, with 14 having CWD. Only one-fifth of the hunters that the Colorado Division of Wildlife expected to check in their heads did so. When you compare the number of hunters with the number of hunters that checked in deer/elk heads, it would appear most hunters didn't care to turn in a submission. So, if there were 14 deer and elk heads from one-fifth, we know that there were many more that went home CWD positive to states all over the country. Those hunters will, or have, eaten some of that meat.

There is a verifiable case CWD that has crossed the borders of Michigan through hunter harvested carcass brought in from out-of state. Three cervids were infected with CWD, two elk and a mule deer, and entered the state as hunter harvested carcasses from Colorado. The hunters submitted the animal heads for testing in Colorado and then transported the carcasses to Michigan. The test results revealed all three were CWD positive. What was left of the carcasses were picked up by the MDNR and incinerated at MSU.

Dosages of CWD transmitting the disease between cervids in research were as low as five grams in scientific research studying transmission of CWD. This research tells us it only takes five grams of CWD infected material to transmit CWD in deer in research laboratories

(See Sigurdson, C.J., E.S. Williams, M.W. Miller, T.R. Spraker, K.I. O'Rourke, and E.A. Hoover. 1999. Oral transmission and early lymphoid tropism of chronic wasting disease PrPres in mule deer fawns (Odocoileus hemionus). Journal of General Virology, 80. pp 2752-2764. - 2 grams of brain orally daily for 5 days (10 grams total) and also see Williams, E.S., M.W. Miller, T.J. Kreeger, R.H. Kahn, and E.T. Thorne. 2002. Chronic Wasting Disease of Deer and Elk: A Review With Recommendations for Management. Journal of Wildlife Management, 66 (3):551-563. Contains the statement"Experimental CWD challenge studies based on single-dose, oral exposure to infectious brain tissue have yielded some insights into disease course; however, because the course of infection may be inversely related to exposure dose (i.e., greater exposure results in shorter duration), experimental data probably underestimate the time frames for most natural infections.)

Now that the issue has been raised in public, more scrutiny will be given to the issues of transporting CWD into the state. We have regulations prohibiting carcass and meat to be brought in over the U.S. and Canadian border as well as carcasses prohibited crossing the Michigan state line. The privately owned cervid industry has viewed the import ban on live animals to be a difficult but prudent measure; however the willingness to allow even portions of animals knowingly taken and imported from CWD positive states seems inconsistent.

It will not be long until a consistent policy to prevent CWD from further entering the state will be called upon to include carcasses, capes, meat, and antlers. A policy supporting surveillance and or testing prior to movement into the state is an appropriate policy for live animals and carcasses, capes, meat, and antlers. The privately owned cervid industry has viewed the import ban on live animals to be a difficult but prudent

measure; however the willingness to allow even portions of animals knowingly taken and imported from CWD positive states seems inconsistent. Beware of those espousing a "zero tolerance" attitude that disfavors movement of carcasses and live animals into the state. That level of risk is impossible in most animal health regulation and is most likely being put forth to erode or diminish positive images of hunting and destroy deer and elk farming by further limiting mark ability of the animals. A proper scientifically defensible standard of "minimal risk", i.e. importation of deboned meat, capes, etc. needs to be developed. If not, a scientifically based explanation requires development to delineate inconsistent agency action towards the goal of keeping CWD from entering our borders.

We need to get a scientific basis for the need to restrict movement of cervid meat. Certainly, there is essentially no risk of translocation of BSE, and virtually no risk of translocation CWD with the movement of venison from commercial and wild cervids. The restriction is inconsistent with interstate movement controls. To date, there are states that ban interstate movement of cervid materials of varying degrees, but one that I know of that is seeking to permanently ban all movement of all venison is New York. I am sure those with an ant-meat, anti-hunting, anti-farming agenda will use the USDA ban as a model for states to follow to ban all movement of venison.

The people of Michigan deserve agency decision maker's base their decisions on input that represents more than subjective beliefs about CWD or unsupported speculation to justify agency action or non-action in response to animal health concerns. Agency decision makers must be motivated to question input from all sources and cannot take on faith that when experts say the evidence supports their conclusions, it must be true. Very often, through statistical manipulation, selective analysis of results or just plain faulty data, conclusions are reached that may be inaccurate and inappropriate for agency reliance. To prevent or discourage agencies from using manipulated data to support hypothesis or justify preconceived conclusions, a recommendation to require agency decision makers to be held accountable for basing their decision on scientifically valid principles is appropriate.